K130455

Section 5: 510(k) Summary

Date prepared: March 7, 2013

Company:

DentalEZ Inc., StarDental Division
Owner/operator number 2520265

SEP 25 2013

Contact Person:

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Proprietary/Trade Name:

430 SWL 45 and 430 SW 45 High-Speed Handpieces

Classification:

Handpiece, Air-powered, Dental (21 C.F.R. § 872.4200, Product code EFB)

Predicate Device:

430 Series High-Speed Handpiece (K960719) manufactured by StarDental

Ti-Max X450 (K112024) manufactured by Nakanishi, Inc.

Impact Air 45 Handpiece for Endodontic Use (K972375) manufactured by Palisades Dental.

The StarDental 430 SWL 45 and 430 SW 45 High-Speed Handpieces have a similar intended use as the predicate Ti-Max X 450 and Impact Air 45 handpieces. The StarDental 430 SWL 45 and 430 SW 45 High-Speed Handpieces incorporates most of the features of the StarDental 430 Series High-Speed Handpiece, however, the intended use of the proposed device has changed to include removal of impacted third molars, endodontic and periodontal procedures.

The methods of operation and technology in the proposed devices are similar to all the predicate devices listed above.

Device Description:

The 430 SWL 45 and 430 SW 45 air-powered high speed handpieces are used by trained dental professionals for the removal of impacted third molars as well as endodontic and periodontal procedures for which a conventional handpiece would be used.

The 430 SWL 45 and 430 SW 45 High-Speed Handpieces are designed with a 45 degree back angled head to facilitate access to the back of the oral cavity. They are designed so that air that expelled from the head of the handpiece is directed out the side of the handpiece head and not directed onto the work area of the bur. The handpieces are intended for use with a friction grip bur that conforms to ISO 1797-1 standards. Recommended air pressure is 30-34 PSI which results in a bur rotation of approximately 400,000 RPM.

The 430 SWL 45 High-Speed Handpiece is a fiber optic, swivel connector type handpiece with a lubefree, ceramic bearing, push button autochuck turbine. The 430 SW 45 High-Speed Handpiece is a non-fiber optic version of the 430 SWL 45 Handpiece.

Intended Use:

The 430 SWL 45 and 430 SW 45 air-powered high speed handpieces are used by trained dental professionals for the removal of impacted third molars as well as endodontic and periodontal procedures for which a conventional handpiece would be used

Technological Characteristics:

The 430 SWL 45 and 430 SW 45 High-Speed Handpieces are air-driven, hand-held devices which have similar technological characteristics to the predicate devices. The proposed devices are swivel connector type handpieces. They incorporate a lubefree, ceramic bearing, push button autochuck turbine assembly. The 430 SWL 45 High-Speed Handpiece is a fiber optic handpiece while the 430 SW 45 is non-fiber optic.

The proposed devices incorporate a 45 degree back angled head to allow for easier access to the third molar which is same as the Ti-Max X450 and Impact Air 45 handpieces.

The following table summarizes the comparison of the 430 SWL 45 and 430 SW 45 High-Speed Handpieces to the predicate devices for various technological characteristics.

Technological Characteristics	**Predicate Device Comparison conclusion**
Indication for use	Similar
Target population	Identical
Design	Similar
Materials	Identical
Performance	Similar
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Similar
Electrical Safety	Not applicable

Non-clinical data:

The 430 SWL 45 and 430 SW 45 High-Speed Handpieces were developed taking into consideration all applicable technical standards, internal specifications and FDA guidance documents. The handpieces conformance with the applicable international and internal standards was verified through bench testing.

TR_468 was developed internally to determine the performance characteristics of the 430 SWL 45 and 430 SW 45 High-Speed Handpieces taking into consideration StarDental internal specifications and ISO 7785-1, 1997-08-01.

TR_470 was developed internally to determine the effectiveness of the housing pressure relief slots and vortex washer on the 430 SWL 45 and 430 SW 45 High-Speed Handpieces. This test request also compared the proposed devices with the predicate devices in order to quantify the air bleed of the handpiece head.

HIGHPOWER Validation Testing & Lab Services of Rochester, NY was contracted to perform sterilization validation and dry time validation studies for the proposed handpieces. These studies were performed in accordance to ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 and AAMI/ANSI/ISO 14937:2009.

A risk analysis for the 430 SWL 45 and 430 SW 45 High-Speed Handpieces was developed using ISO14971:2009.

Substantial Equivalence:

The determination of substantial equivalence is based on the premise that the proposed device and the predicate devices have similarities in intended use, principles of operation, and functional design.

While the intended use of the proposed device and the 430 Series High Speed Handpiece are different, these differences do not raise any new questions of safety or effectiveness and are thus considered substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 25, 2013

DentalEZ Incorporated, StarDental Division
Mr. Jim Watkins
Engineering/Quality Manager
1816 Colonial Village Lane
LANCASTER, PA 17601

Re: K130455
Trade/Device Name: 430 SWL 45 and 430 SW 45 High-Speed Handpieces
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: August 23, 2013
Received: August 27, 2013

Dear Mr. Watkins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

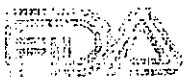
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Richard C. Chapman for

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130455

Device Name: 430 SWL 45 and 430 SW 45 High-Speed Handpieces

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.09.25 09:05:37 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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